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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,098	05/15/2000	ALFREDO NICOSIA	MEWBURN	5857

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MERCK & CO., INC.
126 E. LINCOLN AVENUE
P.O. BOX 2000 (RY60-30)
RAHWAY, NJ 07065-0907

EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,098

Applicant(s)

NICOSIA ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-38, 40, 43-57 and 97-99 is/are pending in the application.
- 4a) Of the above claim(s) 49-57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-48, 98 and 99 is/are allowed.
- 6) ☒ Claim(s) 32-38, 40, 43-44 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Claims 32-38, 40, 43-57 and 97-99 are pending in the application.

Claims 49-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 32-38, 40, 43-48 and 97-99 are under examination.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-38, 40, 43-44 and 97, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that claim 33 was amended to more clearly indicate that the plurality of peptides comprises different peptides, wherein the different peptides comprise a different amino acid sequence within the SEQ ID NO: 39 genus. Support for claim 33 can be found, for example, in the substitute specification on pages 22, line 10 to page 23, line 2.

In response, the as-filed specification, page 22, does not recite for a composition as shown by Formula II, Seq. ID. 39. Rather, a plurality of composition of the 108 different peptides that had been obtained from this formula i.e., all of the species obtained from the generic Seq. ID. 39. (Cf. with claim 45).

Applicants argue that claim 40 was amended to more clearly indicate that each of the different peptides provided by claim 33 consist of said sequence and a hepatitis C virus E2NS1 protein with the peptide in the HVR1 position. Support for the amendment can be found, for example, in the substitute specification on page 19, line 20 to page 20, line 2. The application provides guidance on the use of individual peptides and a mixture of different peptides in a composition, including a pharmaceutical composition. Such guidance is provided, for example, in the substitute specification on pages 41 to 45.

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Pharmaceutical compositions of peptides and mixtures of peptides are referred to, for example, in the substitute specification on page 45, lines 12-22.

In reply, as stated above, the composition refers to the composition comprising of each of the 108 peptides. The claims appear to recite that each of the mixture of 108 different peptides contains, each the Seq. ID. 39, that is a library (as implied in the withdrawn dependent claim 49.) Furthermore, the claims do not recite a pharmaceutical composition but only a composition with Seq. ID. 39.

Withdrawn Rejections

In view of the amendments to the claims and applicants' arguments, the rejections under 35 USC 112, second paragraph, 35 USC 102 and 103 over Puntoriero et al are withdrawn.

Applicants request clarification or confirmation of the status of the original restriction requirement. It is applicants understanding that claims 32-38, 40, 43-46 and 97-99 are under examination as part of the elected Group II. Group II contains claims directed to a mixture of polypeptides (claim 32-38, 40, 43 and 44) and polypeptides falling within Formula II (claim 45). In addition, claim 46 providing a generic claim that encompasses the elected species (Formula 11) is under examination. Claims 47-57 are currently withdrawn from

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prosecution as non-elected species within Group II. Applicants' understanding is based on the original restriction requirement provided June 4, 2001 and subsequent actions. The original restriction requirement included Group II claims 32-57, which was characterized as drawn to a mixture of peptides obtainable from a library, and the following different species under Group 11: (A) Formula 11 or in composition form; (B) fusion composition; and (C) pharmaceutical composition. Applicants elected Group 11, species A, and indicated that then pending claims 32-38 read on the elected species. (Response dated July 5, 2001.) Subsequently in an office action dated May 3, 2002, claims 46-57 and subject matter not drawn to Formula 11 were indicated to be withdrawn from prosecution. The remaining claims under examination (claims 32-45) included both mixture claims and polypeptide claims. In a response dated August 2, 2002, applicants requested that claim 46 also be examined in the present application. Claim 46 is directed to a polypeptide of Formula 1, which generically covers the elected species (Formula II).

In response, since the generic peptide sequence of claim 45 (Seq. ID. 39) is found allowable (see below), the species of claim 47 and claim 48, which has been withdrawn, has been rejoined and examined together with the examined Group II

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(claims 32-38, 40, 43-46 and 97-99). However, claim 49 and the dependent claims are withdrawn since this is drawn to a peptide obtained from the process of claim 1 (a cancelled claim). (It appears that these claims are the same except for the preamble recited in each of the claims. For example, claims 33, 39 and 45 are all drawn to the same Seq. ID. 39 except claim 33 recite the preamble as a mixture. Claim 39 recites a composition and claim 45 recites a peptide. Each claims recites the same formula of Seq. ID. 39. As apparent from the disclosure, these are all peptides of Seq. ID. 39. Likewise, claims 47 and 49 are but one and the same compound species.)

Allowable Subject Matter

Claims 45-48 and 98-99 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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T.D. 7
T. D. Wessendorf
Primary Examiner
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tdw

May 15, 2004